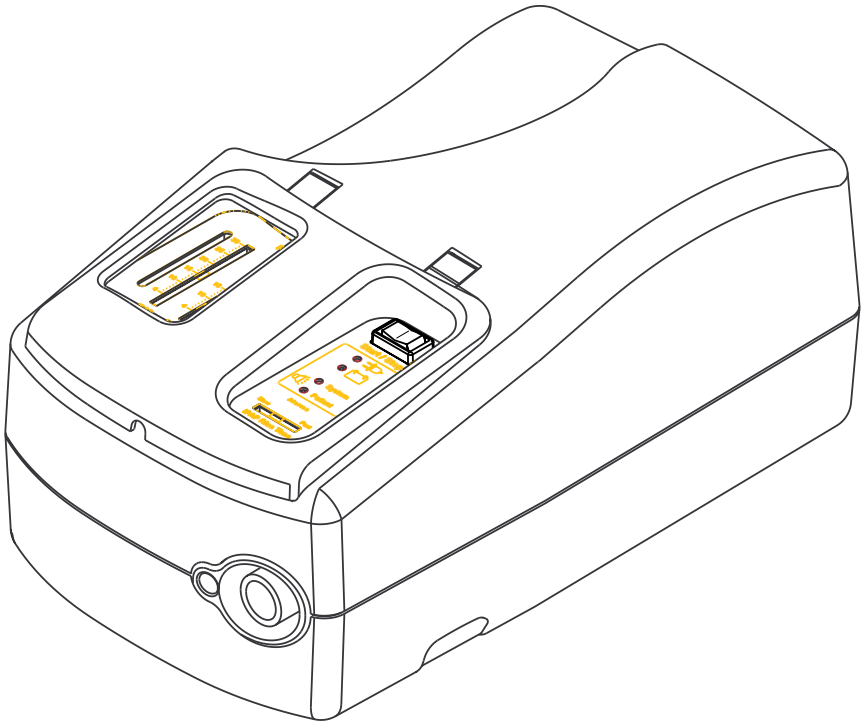
BiPAP® *Harmony*™ *S/T*
Ventilatory Support System

Clinical Manual



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Chapter 1: Introduction

1.1 Harmony S/T Overview

The Harmony™ S/T ventilator, shown in Figure 1-1, is a low-pressure, electrically driven ventilator system with electronic pressure control. The unit's pressure controls are adjusted to deliver pressure support for patient ventilatory assistance.

The Harmony S/T ventilator is intended to augment patient breathing by supplying pressurized air through a patient circuit. It senses the patient's breathing effort by monitoring airflow in the patient circuit and adjusts its output to assist in inhalation and exhalation. This assistance is provided by the administration of two levels of positive pressure. During exhalation, pressure is variably positive or near ambient. During inspiration, pressure is variably positive and always higher than the expiratory level.

The Harmony S/T ventilator responds reliably to patient flow rates that indicate movement to inhalation or exhalation, even in the presence of most normal leaks in the patient circuit. Automatic adjustment of this trigger threshold in the presence of leaks makes the system ideal for mask-applied ventilation assistance.

The ventilator operates in the Spontaneous/Timed (S/T) mode. The S/T mode is introduced in Section 1.2.

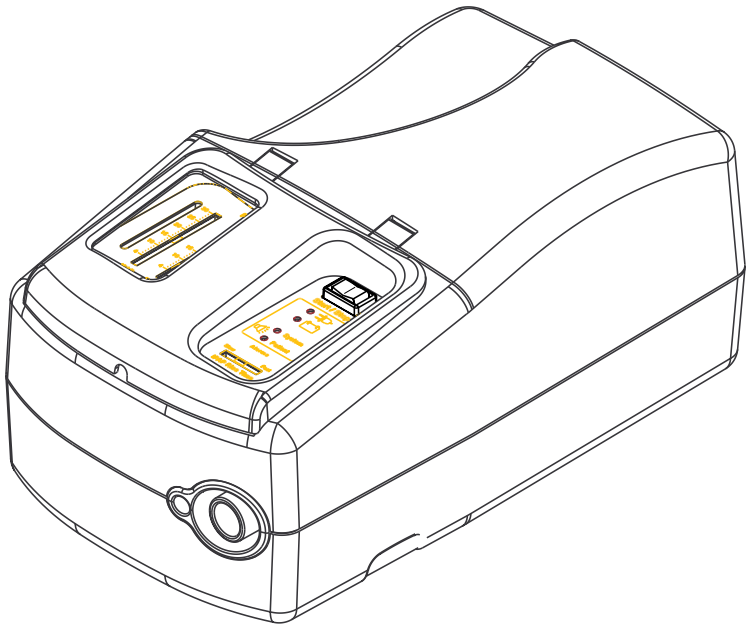


Figure 1-1. The BiPAP Harmony S/T Ventilator.

1.2 S/T Mode

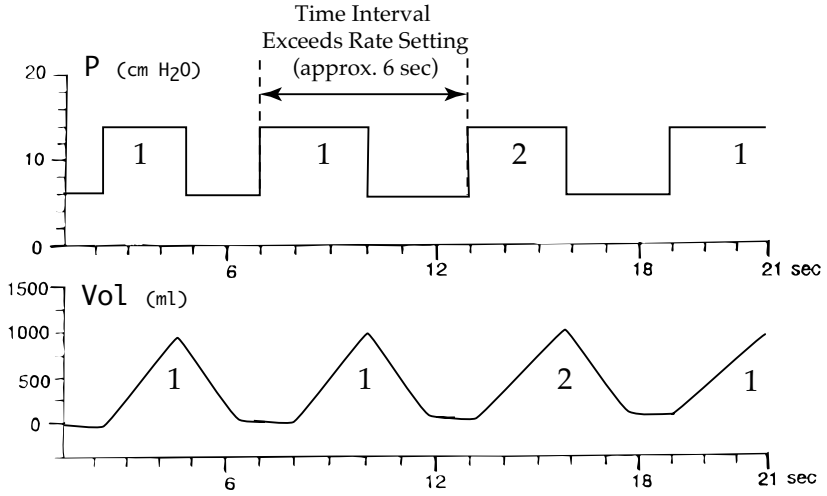
The ventilator's S/T mode delivers pressure support with Positive End Expiratory Pressure (PEEP). The unit triggers Inspiratory Positive Airway Pressure (IPAP) in response to spontaneous inspiratory effort and cycles to Expiratory Positive Airway Pressure (EPAP) during exhalation.

The level of pressure support (PS) delivered is determined by the difference between the IPAP and EPAP settings (PS = IPAP - EPAP).

The S/T mode ensures that patients will receive a minimum number of breaths per minute if their spontaneous breathing rate drops below the Rate setting. If the patient fails to initiate an inspiration within the interval determined by the Rate control, the unit triggers a timed breath resulting in a pressure-control (pressure-limited, time-cycled) breath at the set IPAP level. The rate of timed breaths can be adjusted from 4 to 30 BPM and the duration of each breath is controlled by an Inspiratory Time control. See Figure 1-2 for an example of patient-triggered and machine-triggered breaths.

Example:

IPAP = 14 cm H_2O
EPAP = 6 cm H_2O
Rate = 10 BPM
PS = 8 cm H_2O



1 = Spontaneously-triggered pressure support breaths.
2 = Time-triggered, pressure-limited, time-cycled breath.

Figure 1-2. Example of Patient-Triggered and Machine-Triggered Breaths.

1.3 Manual Overview

This manual describes the Harmony S/T ventilator and its operation.

Chapter 1 Introduces the Harmony S/T ventilator.

Chapter 2 Lists the Warnings, Cautions, Notes and Contraindications for the Harmony S/T. Also contains information concerning rebreathing.

Chapter 3 Provides an overview of the controls, connections, and outputs.

Chapter 4 Provides the set up, start-up, and operating procedures for the Harmony S/T and details the operation of the S/T mode.

Chapter 5 Describes the alarms and alarm conditions and provides troubleshooting guidelines for mask discomfort.

Chapter 6 Provides information for adding oxygen to the Harmony S/T patient circuit.

Chapter 7 Provides cleaning instructions and routine maintenance procedures.

Chapter 8 Describes the accessories and circuits to be used with the Harmony S/T.

Chapter 9 Lists the Harmony S/T specifications.

Chapter 10 Describes the Harmony S/T performance verification.

NOTE: Illustrations are for reference only. Occasionally, cosmetic changes may be made to the product that do not affect the performance or specifications of the product. These kinds of changes do not warrant a reprinting of this manual, so the illustrations may differ slightly from your unit.

1.4 Symbol Key

The following symbols are used on the Harmony S/T ventilator:

Symbol	Meaning
	Attention, consult accompanying documents
	AC Power Indicator
	DC Power Indicator
	Alarms
	Patient Disconnect Alarm Disabled
	System Alarm Indicator
	Patient Alarm Indicator
	START
	STOP
	Time at Pressure
	Rise Time control (patient comfort)
f	**Breaths Per Minute setting**
T_i	**Inspiratory Time Setting**
	Type BF Applied Part
	Class II for Protection Against Electric Shock
O_2	**Oxygen Valve**
	Inlet (Optional Oxygen Valve)
	Outlet (Optional Oxygen Valve)

1.5 Product Support

You may contact Respironics, Inc. with any questions or for product support at:

RESPIRONICS INC.®
1001 Murry Ridge Lane
Murrysville, Pennsylvania
15668-8550 U.S.A.

RESPIRONICS®
Deutschland
Gewerbestrasse 17
82211 Herrsching Germany

Chapter 2: Warnings, Cautions, and Notes

WARNING: Indicates the possibility of injury to the patient or the operator.
CAUTION: Indicates the possibility of damage to the device.
NOTE: Places emphasis on an operating characteristic.

2.1 Warnings

- This manual serves as a reference. The instructions in this manual are not intended to supersede the institution's protocol regarding the use of the BiPAP Harmony S/T ventilator.
- The Harmony S/T provides positive pressure ventilation and is indicated for assisted ventilation. This system does not provide ventilation with guaranteed tidal volume delivery. Patients requiring ventilation at predetermined tidal volumes are not candidates for pressure support ventilation.
- The Harmony S/T requires an intentional leak port (exhalation port) instead of an actively-controlled exhalation valve to remove exhaled gases from the circuit. Some Respironics masks have integrated exhalation ports and do not require the use of a separate exhalation device. If the mask or flexible tubing does not have an integrated exhalation port, an exhalation device must be added to the circuit. The pressurized air from the Harmony S/T causes a continuous flow of air to exhaust from the leak port, flushing exhaled gas from the circuit. The machine should be turned on and the intentional leak port should be checked before application.
- The continuous flow of air through the leak port flushes exhaled gases from the circuit. The ability to completely exhaust exhaled gas from the circuit is dependent upon the EPAP setting and I:E ratio. At low EPAP pressures or with short expiratory times (i.e., high breathing rates), the leak rate through the intentional leak port may be inadequate to clear all exhaled gas from the circuit. Some rebreathing may occur.
- If the patient is using a full face mask with the Harmony S/T ventilator, an entrainment valve must be used in the patient circuit to minimize the possibility of rebreathing CO_2.
- The Harmony S/T ventilator is intended for use with a Respironics, Inc. patient circuit only. See Chapter 8 for approved patient circuit configurations and accessories.
- Proper operation of the Plateau™ Exhalation Valve or any other exhalation port used with the Harmony S/T must be regularly verified by inspection during use. Occlusion or partial occlusion of the exhalation port may result in asphyxia.
- To reduce the risk of contamination, a low resistance main flow bacteria filter may be placed in-line between the unit and the patient. If the bacteria filter is used, verify its proper operation. Occlusion or partial occlusion can result in reduced air flow.

Warnings (continued)

- All patient settings must be determined via appropriate assessment and monitoring as determined by the prescribing physician.
- The Harmony S/T ventilator is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
- If supplemental oxygen is added to the breathing circuit, the optional oxygen valve must be installed and used as shown in Chapter 6. The valve automatically stops the flow of oxygen if the Harmony S/T power is off.
- The functionality of this machine may be adversely affected by the operation of high frequency (diathermy) equipment, defibrillators, or short wave therapy equipment in the general vicinity.
- Do not use antistatic or electrically conductive hoses or tubing with the Harmony S/T system.
- In the event of a power failure, an audible/visual alarm will activate. Disconnect the Harmony S/T ventilator from the patient immediately. As in most ventilators with passive exhalation ports, when power is lost, sufficient air will not be provided through the circuit and exhaled air may be rebreathed.
- The air flow for breathing produced by this device can be as much as 10° C (18° F) higher than room temperature. Caution should be exercised if the room temperature is greater than 40 °C (104 °F).
- When the Harmony S/T ventilator is used with a humidifier, always position the humidifier lower than both the ventilator and the patient.
- When administering supplemental oxygen, a controlled method of setting and measuring inspired oxygen concentrations cannot be accomplished. At a fixed flow of supplemental oxygen, the inspired oxygen concentration will vary, depending on the IPAP and EPAP settings, patient breathing pattern, and the leak rate. Substantial leaks around the mask may reduce the inspired oxygen concentration to less than the expected concentrations shown in Chapter 6. Continuous patient monitoring is recommended while administering supplemental oxygen.

  Patient monitoring should consist of, as a minimum, patient observation and pulse oximetry. Arterial blood gas measurements should be used when necessary.
- When using supplemental oxygen, the oxygen line flow meter should be compensated, i.e., flow reads zero if there is an occlusion after the flow meter. Also, the oxygen supply should be observed after each use to ensure that the gas contents have been reduced. These measures will indicate if the Respironics oxygen valve fails in the closed position, which would stop oxygen flow from reaching the patient.

Warnings (continued)

- If you detect any unexplained changes in the performance of the Harmony S/T ventilator, seek the assistance of Respironics, Inc. or an authorized service center.
- Repairs and adjustments must be performed by Respironics, Inc. or an authorized service center. Service done by inexperienced, unqualified personnel or installation of unauthorized parts could cause injury, invalidate the warranty, or result in costly damage.
- Electrical cords and cables should be periodically inspected for damage or signs of wear.
- To avoid electrical shock, unplug the Harmony S/T unit before cleaning it.
- If the Harmony S/T ventilator is dropped or mishandled, the unit must be checked by a qualified technician.
- Avoid exposing the Harmony S/T ventilator to non-ionizing radiation (e.g., x-ray, CT) and to magnetic fields (e.g., MRI).
- Inspect the patient circuit before each use to verify that the patient circuit is not occluded.
- The patient must be capable of removing the mask in the event of a problem with the Harmony S/T ventilator.

2.2 Cautions

- Avoid exposure of the Harmony S/T ventilator to temperatures at or near the extremes of those specified in Chapter 9. If exposure to such temperatures has occurred, the unit should be allowed to come to room temperature before being turned on.
- For proper operation, the unit must be placed on its base with its cooling and exhaust vents unoccluded.
- Do not operate the Harmony S/T ventilator in direct sunlight.
- The functioning of the Harmony S/T ventilator can be adversely affected by electromagnetic interference exeeding the level of 10 V/m in the test conditions of EN 60601-1-2.
- Always use the recommended inlet filter when the Harmony S/T ventilator is operating.
- If the External Battery Discharged Alarm is activated, disconnect the external battery immediately. A discharged battery may be damaged if it continues to be connected to the ventilator.

2.3 Notes

- The Inspiratory Positive Airway Pressure (IPAP) and Expiratory Positive Airway Pressure (EPAP) controls are coupled. The unit will not deliver an EPAP level that is higher than the set IPAP level.

Additional Warnings, Cautions, and Notes are located throughout this manual.

2.4 Intended Use

The Harmony S/T ventilator is a noninvasive, pressure support ventilator used to augment the breathing of adult patients (> 30 kg) suffering from acute or chronic respiratory insufficiency, or to maintain airway patency and provide ventilatory support to patients who experience obstructive sleep apnea. The Harmony S/T is not intended to provide the total ventilatory requirements of the patient.

The Harmony S/T is intended for use in the home, hospital, or alternate care settings.

2.5 Contraindications

The use of the Harmony S/T ventilator is contraindicated on patients without a spontaneous respiratory drive.

The use of the Harmony S/T ventilator for noninvasive positive pressure therapy may be contraindicated on patients:

- unable to maintain a patent airway or adequately clear secretions,
- at risk for aspiration of gastric contents,
- with acute sinusitis or otitis media,
- with a history of allergy or hypersensitivity to the mask materials where the risk from allergic reaction outweighs the benefit of ventilatory assistance,
- with epistaxis, causing pulmonary aspiration of blood, or
- with hypotension.

2.6 Patient Precautions

- Advise the patient to immediately report any unusual chest discomfort, shortness of breath, or severe headache.
- If skin irritation or breakdown develops from the use of the mask, refer to the mask instructions for appropriate action.
- The following are potential side effects of noninvasive positive pressure therapy:
  - —Ear discomfort
  - —Conjunctivitis
  - —Skin abrasions due to noninvasive interfaces
  - —Aerophagia (gastric distention)

Chapter 3: Controls

This chapter describes the panel controls and displays, the patient circuit connections, and the rear panel connections and controls.

3.1 Control Panel

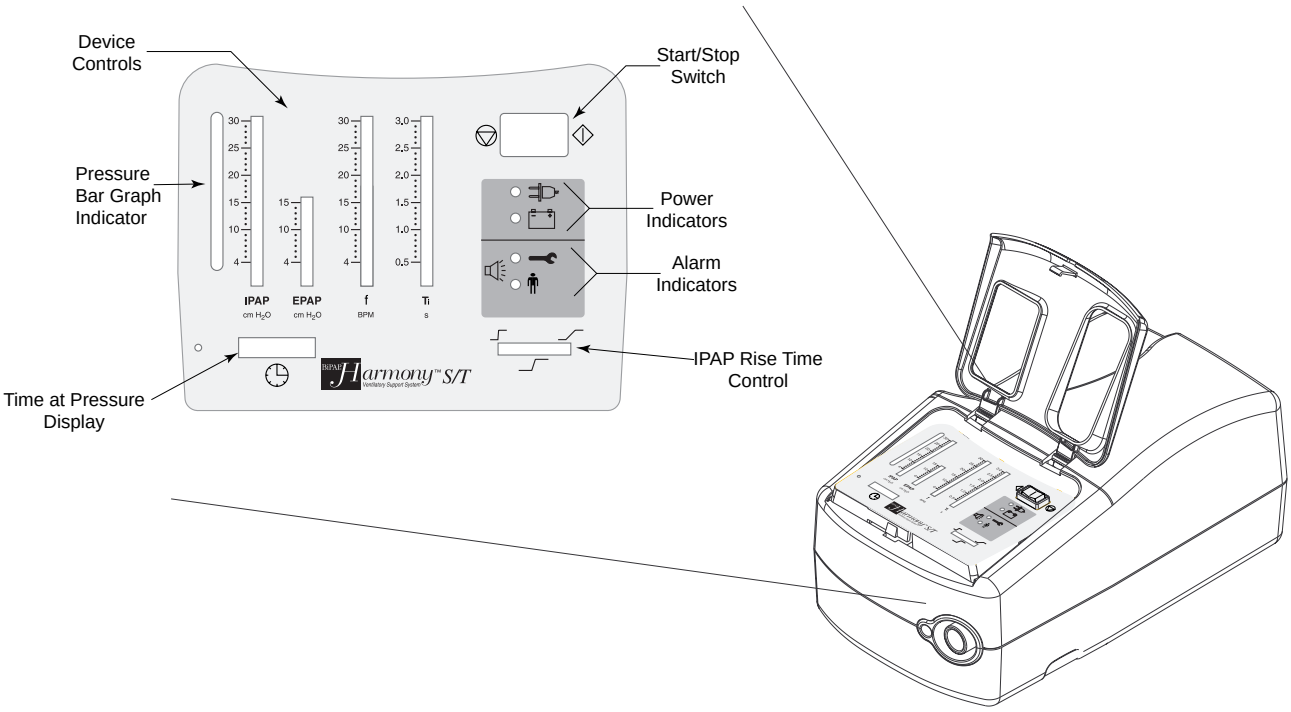


Figure 3-1. The Harmony S/T Control Panel.

Figure 3-1 illustrates the Harmony S/T control panel. The control panel includes:

- device controls (slide controls with LED indicators)
- pressure bar graph indicator
- Time at Pressure display
- Start/Stop switch
- power indicators (AC and DC)
- alarm indicators (System and Patient)
- IPAP Rise Time control

The device controls are inaccesible to the patient. To access the controls, you must use a tool to unlatch and open the door. See Section 4.2.1. When the door is closed, the pressure bar graph and the IPAP and EPAP slide controls can be viewed through a window in the door.

3.1.1 Device Controls

Values are set with illuminated slide controls. The top edge of the control indicates the value of the parameter on the adjacent scale.

IPAP Control

NOTE: The IPAP value should not be set lower than the EPAP value. If you attempt to set IPAP lower than EPAP, the unit will only deliver pressure at the IPAP level.

- Adjusts the pressure level for the inspiratory phase
- Range: 4 to 30 cm H_2O
- Steady illumination during IPAP phase
- Blinking illumination if IPAP is set lower than EPAP

EPAP Control

- Adjusts the baseline expiratory pressure (PEEP)
- Range: 4 to 15 cm H_2O
- Steady illumination during EPAP phase
- Blinking illumination if IPAP is set lower than EPAP

NOTE: The Rate control and the Timed Inspiration Control are linked so that the inspiratory time is never longer than the expiratory time, or greater than 3 seconds. If the Rate is increased to a value that would exceed a 1:1 I:E ratio, the Timed Inspiration control would be automatically reduced to maintain a 1:1 I:E ratio.

Rate Control

- Adjusts the frequency of timed breaths
- Range: 4 to 30 BPM
- Steady illumination during timed breath
- Blinking illumination if settings cause inspiratory time to exceed expiratory time

NOTE: The blinking illumination is used to indcate gross inspiratory time mismatches only. Do not use the blinking illumination to set the inspiratory time.

Timed Inspiration Control

- Adjusts the duration of the inspiratory phase of a timed breath
- Range: 0.4 to 3.0 seconds
- Blinking illumination if settings cause inspiratory time to exceed expiratory time

3.1.2 Pressure Bar Graph Indicator

The Pressure Bar Graph indicator changes height in response to the pressure output level. It is used to show the change between IPAP and EPAP. It is not intended to be used for pressure measurement.

3.1.3 Time at Pressure Display

The Time at Pressure display is an LCD time meter that indicates the accumulated hours of patient therapy, in 0.1 hour increments. The display can be reset by inserting a pin through the hole in the control panel.

3.1.4 Start/Stop Switch

The Start/Stop rocker switch starts and stops the unit.

3.1.5 Power Indicators

The power indicators show the presence and source of power connected to the Harmony S/T unit. The top indicator illuminates for AC power; the bottom indicator illuminates for DC power.

3.1.6 Alarm Indicators

Two Alarm Indicators are included: System and Patient. The System Alarm Indicator lights when an internal error is detected or power is lost. The Patient Alarm Indicator lights when a patient disconnect is detected. See Chapter 5 for an explanation of all alarms.

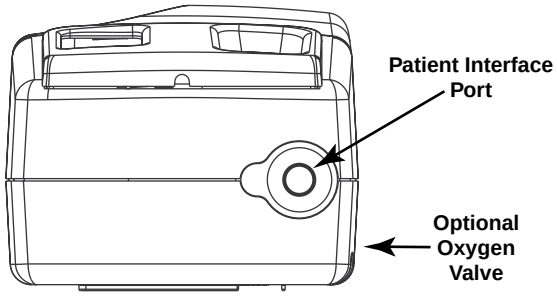
3.1.7 IPAP Rise Time

The IPAP Rise Time control varies the rate of change (slow to fast) of pressure during the transition from EPAP to IPAP.

The IPAP Rise Time control is intended as a patient comfort control.

3.2 Patient Circuit Connection

The patient circuit is connected to the Patient Interface port.

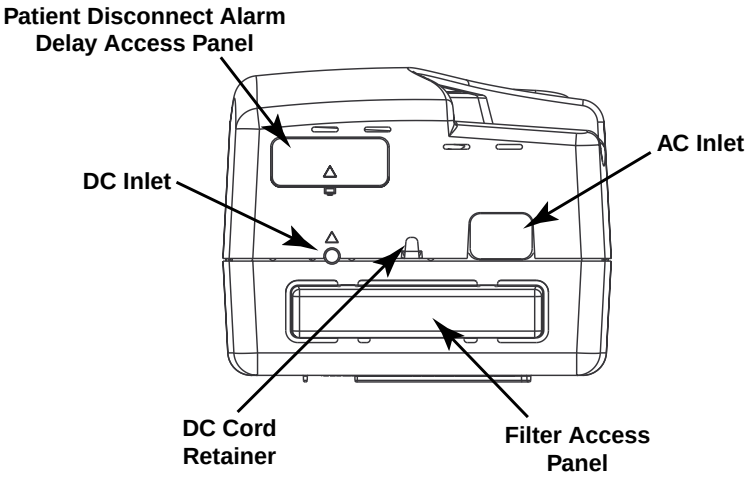


The Patient Interface port accepts a 22 mm I.D. tubing or an optional 22 mm I.D. bacteria filter.

3.3 Rear Panel

The rear panel contains:

- Patient Disconnect Alarm Delay access panel
- AC inlet
- DC inlet
- Filter access panel



3.3.1 Patient Alarm Access Panel

This panel is removed to adjust the patient disconnect alarm delay time. See Chapter 4 for details.

3.3.2 AC Inlet

The AC inlet is where the AC power cord (100 to 240 Vac) is inserted.

3.3.3 DC Inlet

The DC inlet is where the DC power cord (12 Vdc) is inserted.

3.3.4 Filter Access Panel

This panel is removed to access the inlet air filters. See Chapter 7 for details.

3.3.5 DC Cord Retainer

The DC cord retainer provides strain relief for the DC power cord.

3.4 Optional Oxygen Valve

The Harmony S/T ventilator optional oxygen valve is mounted to the side of the unit, as shown in Figure 3-2. The valve must be used if low flow oxygen is to be titrated into the breathing circuit of the Harmony S/T ventilator. See Chapter 6 for instructions.

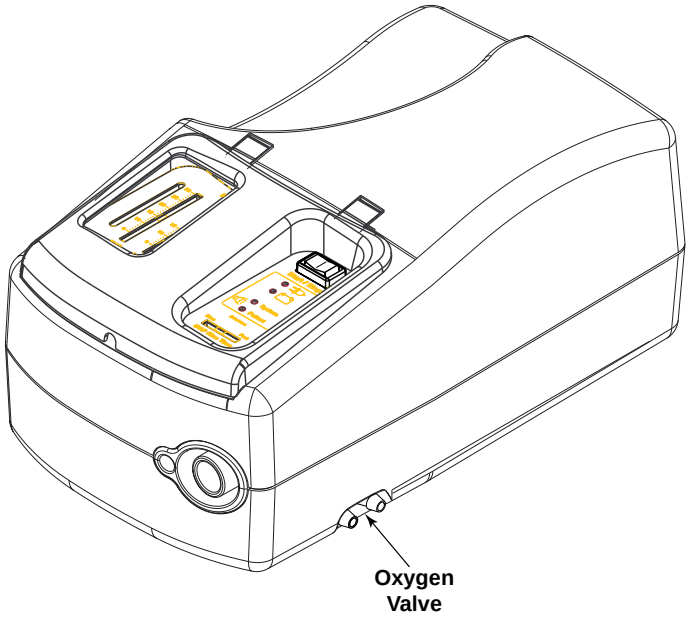


Figure 3-2. Location of Oxygen Valve.

3.5 Air Vent

The air vent, located on the bottom of the unit, allows the excess air that is vented from the internal control valve to leave the unit.

Chapter 4: Setting Up and Starting the Harmony S/T Ventilator

4.1 Setting Up the Harmony S/T Ventilator

4.1.1 Installing the Filters

The Harmony S/T ventilator uses two removable filters at the air inlet. You must install these filters before operating the Harmony S/T ventilator. The gray pollen filter is washable and reusable. The optional white ultra-fine filter is disposable.

Step 1 Place the pollen filter on top of the ultra-fine filter.

Step 2 Slide the filters into the air inlet at the rear of the unit as shown in Figure 4-1.

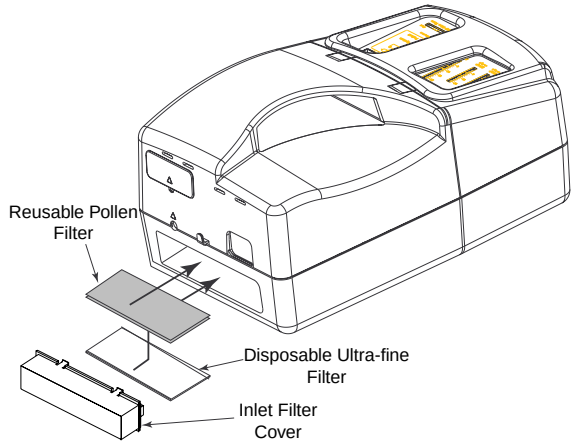


Figure 4-1. Installing the Air Filters.

Step 3 Place the bottom of the inlet filter cover into the bottom of the air inlet opening, making sure that the catches engage the lip of the opening.

Step 4 Swing the top of the cover into place and press down on the cover to engage the catches in the air inlet opening.

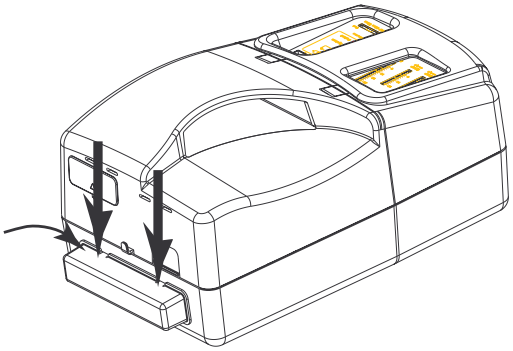


Figure 4-2. Replacing the Filter Cover.

WARNING: The exhalation port (e.g., the Whisper Swivel® II) is designed to exhaust CO_2 from the patient circuit. Do not block or seal the gas vents on the exhalation port.

WARNING: The oxygen valve must be installed and used if oxygen is to be titrated to the patient circuit. See Chapter 6 for complete details.

NOTE: Each time changes are made to the circuit configuration, confirm the set and delivered pressures.

NOTE: When setting up a patient on the Harmony device, please ensure that--in addition to following the setup guidelines detailed in this manual--you have the patient (when breathing spontaneously) trigger the ventilator to IPAP (Inspiration) and cycle to EPAP (Expiration). During setup it is important to ensure that the ventilator is in synchrony with the patient's ventilatory needs and breathing pattern.

4.1.2 Assembling the Patient Circuit

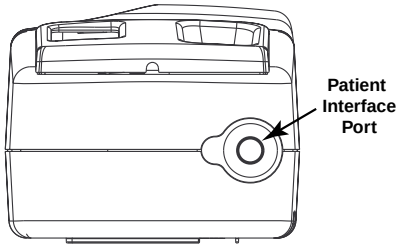


Figure 4-3. Patient Interface Port.

Step 1 Assemble the patient circuit according to the configurations presented in Chapter 8.

Step 2 If required, connect a bacteria filter to the Patient Interface Port (shown in Figure 4-3), and connect the patient tubing to the outlet of the bacteria filter.

If the bacteria filter is not required, connect the patient tubing directly to the Patient Interface Port.

If oxygen is to be used, connect it now according to Chapter 6.

A completed assembly is shown below.

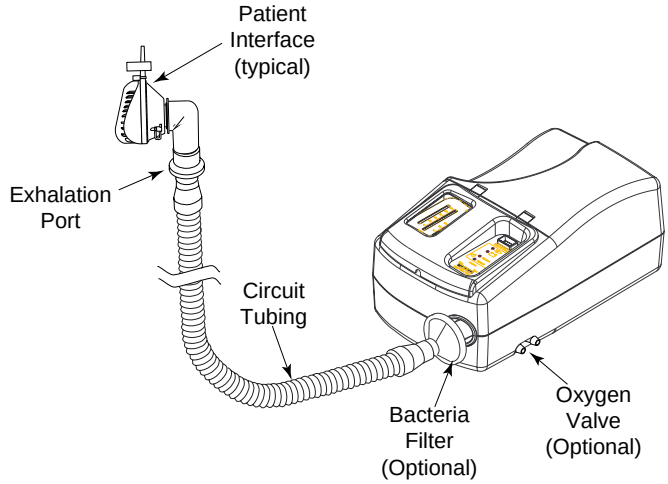


Figure 4-4. An example of a Respironics-approved circuit.

4.2 Setting the Prescription

4.2.1 Setting the Patient Parameters

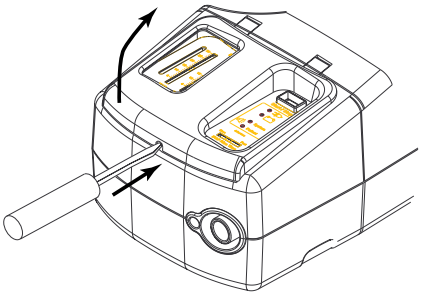


Figure 4-5. Opening the Parameter Door.

Step 1 Use a small flat blade screwdriver to unlatch the parameter door.

Step 2 Slide the patient setting controls to the prescribed settings.

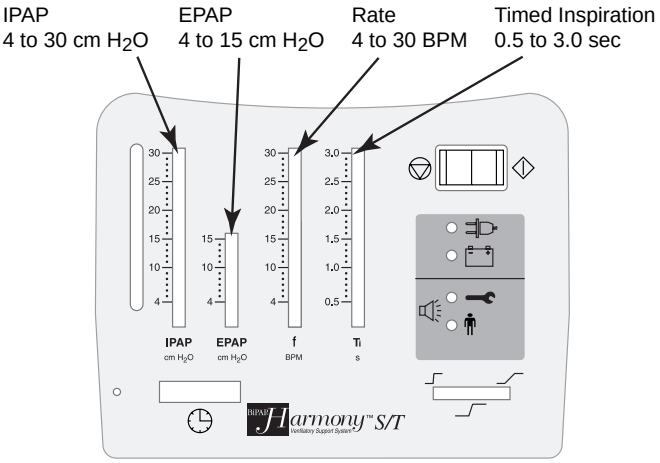


Figure 4-6. Patient Settings.

- When the unit is started, if IPAP is set lower than EPAP, both control LEDs flash, and the pressure output is set to the IPAP level.
- When the unit is started, if the Rate or Timed Inspiration have values that would cause the I:E ratio to be greater than 1:1, both control LEDs flash and the I:E ratio is set to 1:1.

NOTE: The control LEDs are used to indicate gross inverse I:E ratios. Do not use the control LEDs to set the inspiratory time.

Step 3 Close the parameter door and be sure it latches.

NOTE: Before placing the patient interface on a patient, verify the output pressures with a manometer connected at the patient interface.

4.2.2 SETTING THE PATIENT DISCONNECT ALARM DELAY

WARNING: Always disconnect the Harmony S/T from the power source before opening the access panel.

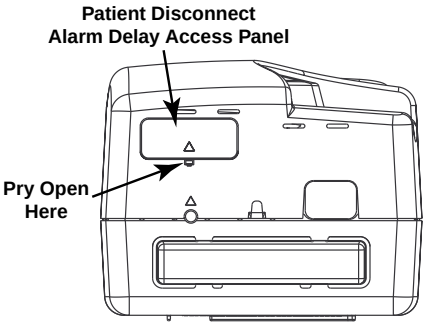


Figure 4-7. Opening the Access Panel.

STEP 1 Disconnect the Harmony S/T from the power source.

STEP 2 Pry open the access panel with a small screwdriver.

NOTE: Always verify that the Patient Disconnect Alarm functions properly when the patient circuit is connected.

STEP 3 Set the switch to the desired delay setting:

- 60 sec
- 15 sec
- Disabled

See Chapter 5 for an explanation of the Patient Disconnect alarm.

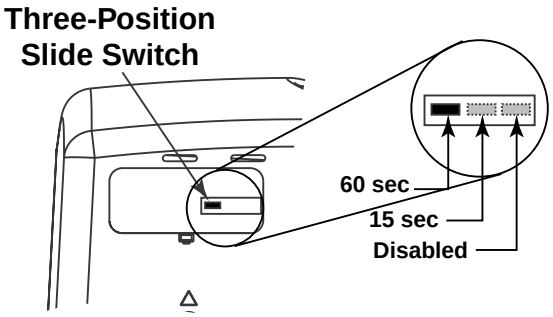


Figure 4-8. Patient Disconnect Alarm Delay Settings.

STEP 4 Replace the access panel.

4.3 Operating the Harmony S/T Ventilator

4.3.1 AC Operation

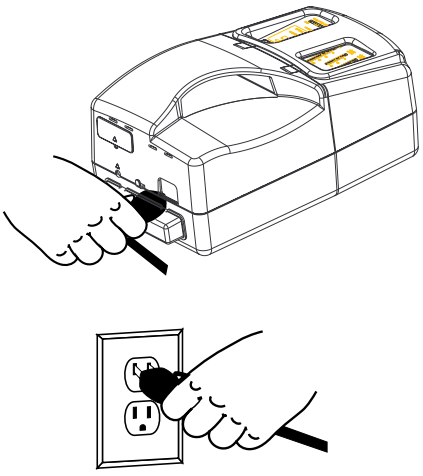


Figure 4-9. Plugging in the AC Cord.

Step 1 Follow the procedure in section 4.1.2, Assembling the Patient Circuit.

Step 2 Plug the electrical cord into the AC inlet in the back of the Harmony S/T unit.

Step 3 Verify that the Start/Stop switch is in the **STOP** position, then plug the electrical cord into an outlet that is not controlled by a wall switch.

Step 4 Set the patient's prescription (see Section 4.2) before applying the patient interface to the patient.

NOTE: The use of an electrical adaptor or extension cord is not recommended.

4.3.2 DC Operation

CAUTION: Only use a Respironics-supplied DC cord.

Step 1 Follow the procedure in section 4.1.2, Assembling the Patient Circuit.

Step 2 Plug the DC cord connector into the rear of the Harmony S/T ventilator.

Step 3 Leaving a small amount of slack in the cord, press the cord into the DC cord retainer.

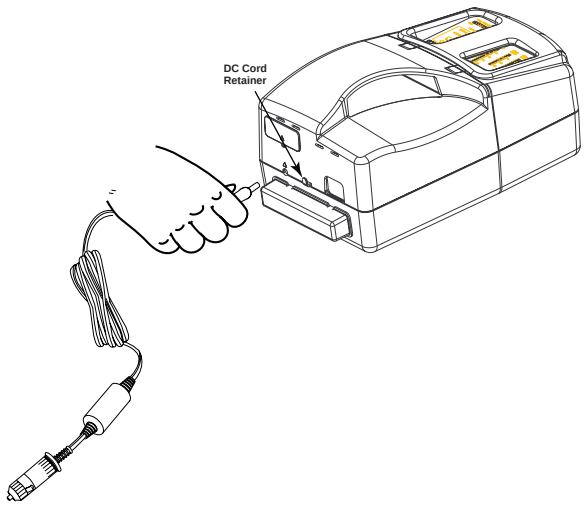


Figure 4-10. Plugging in the DC Cord.

Step 4 Connect the DC cord to the appropriate DC source.

Refer to the DC cord instruction sheet for recommended DC power sources.

Step 5 Set the patient's prescription (see Section 4.2) before applying the patient interface to the patient.

4.3.3 CONNECTING THE PATIENT

NOTE: Before placing the patient interface on the patient, check the integrity of the patient circuit and the exhalation port.

STEP 1 Place the interface device on the patient.

STEP 2 If oxygen is being used, turn on the oxygen flow. Always turn the Harmony S/T ventilator on before turning on the oxygen, and always turn the oxygen off before turning off the Harmony S/T ventilator.

STEP 3 Place the Start/Stop switch in the **START** position.

The Harmony ventilator initiates a self-test. All LED indicators light momentarily and the audible alarm beeps twice to verify that the audible alarm is functioning. If the indicators do not light, or the audible alarm does not beep twice, the unit requires service.

STEP 4 After the self-test, the unit begins operation.

If any control LED is blinking, a parameter is set incorrectly:

NOTE: During normal operation, the IPAP and EPAP controls should illuminate steadily during the appropriate breathing phase. The Rate control should illuminate steadily only when a machine-triggered breath is delivered.

- Blinking IPAP and EPAP controls mean that the IPAP has been set at a value lower than EPAP. The unit will deliver CPAP at the IPAP setting.
- Blinking Timed Inspiration and Rate controls mean that the Inspiratory time exceeds the Expiratory time. The unit will not allow the I:E ratio to exceed 1:1 for a machine-triggered breath.

See Chapter 5 for alarm information.

See Chapter 6 if you are administering oxygen to the patient.

Chapter 5: Alarms

This chapter describes the Harmony S/T alarms and lists possible corrective actions for the alarm conditions.

The Harmony S/T ventilator provides two alarm levels: high priority and warning. High priority alarms require immediate attention and consist of a System or Patient LED on and an audible alarm that is either continuous or sounds a pattern of three beeps followed by two beeps, which is repeated after a short pause; the ten beep pattern is repeated every five seconds.

Warning alarms are less critical and consist of a flashing LED and an audible alarm that sounds three beeps every 15 or 30 seconds, depending on the cause of the alarm.

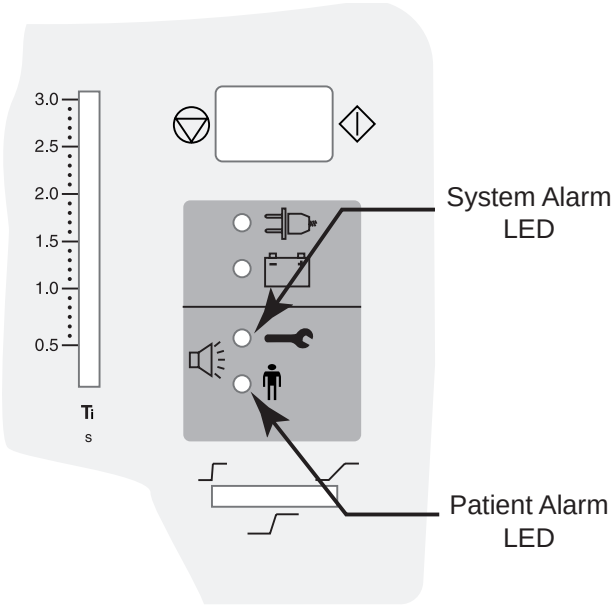


Figure 5-1. System and Patient Alarm LEDs.

Table 5-1 lists the alarm indicators, the possible conditions for each alarm, and the corrective action for each alarm.

LED Indicator	Audible Indicator[1]	Cause	Machine Action	Corrective Action
System Alarms				
System LED on (AC & DC LEDs off)	Continuous	Loss of input power	Shutdown	Check power source
System LED on	Continuous	Internal critical error	Shutdown	Service unit
System LED on	Continuous	Internal power supply failure	Shutdown	Service unit
System LED on	High Priority	Pressure regulation-low	Operates	Check inlet filters, or service unit
System LED on	High Priority	Pressure regulation-high	Shutdown	Service unit
System LED on	High Priority	Outlet overpressure	Shutdown	Service unit
System LED on	High Priority	Motor fault	Shutdown	Service unit
System LED on	High Priority	Outlet pressure low	Operates	Service unit
DC Power Alarms				
Flashing DC	Warning, 30 second repeat	Switchover to DC power from AC power	Operates	Reconnect AC and restart, or disconnect AC and restart on DC
Flashing DC	Warning, 15 second repeat	Low external battery	Operates	External battery failure imminent, seek alternate power source
System LED on	Continuous	External battery discharged	Shutdown	Replace external battery or seek alternate power source
Patient Alarm				
Patient LED on	High Priority	Patient disconnect (excessive flow)	Operates	Check for excessive leak or replace mask, reconnect circuit

[1]Audible Alarm Indicators:

- **Continuous:** Alarm is always on.
- **High Priority:** Alarm sounds three beeps followed by two beeps, repeats after a short pause, then repeats the ten beep pattern every five seconds.
- **Warning:** Alarm sounds three beeps and repeats every 15 or 30 seconds, depending on cause of alarm.

Table 5-1. Harmony S/T Alarm Conditions and Corrective Actions.

Chapter 6: Adding Supplemental Oxygen

You may add supplemental oxygen directly to the patient circuit. This chapter describes the method of oxygen delivery and shows the oxygen concentrations attained at various IPAP and EPAP settings and oxygen flow rates.

WARNING: Oxygen should be administered only on the order of a physician.

WARNING: Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.

6.1 Adding Supplemental Oxygen

Low-flow oxygen may be added to the patient circuit at the air outlet or at the mask.

WARNING: If supplemental oxygen is added to the breathing circuit, the optional oxygen valve must be installed and used as shown in Figure 6-1. If the Harmony S/T air flow stops, the valve automatically closes, preventing high levels of oxygen concentration from entering the unit case.

The delivered oxygen concentration varies with changes in flow in the circuit. The following may impact oxygen concentration:

- Pressure settings
- Patient Tidal Volume
- Peak Inspiratory Flow
- I:E Ratio
- Respiratory rate
- Circuit leak rate
- Oxygen flow rate
- Site where oxygen is added to the circuit

To add oxygen to the circuit, a controlled, low flow source is needed. An oxygen source governed by a compensated flow meter assembly should be used. Testing has shown that the performance of the system is not affected by the addition of a low flow (up to 15 L/min) oxygen source to the patient circuit.

Step 1 As shown in Figure 6-1, attach oxygen tubing from the oxygen source to the rear oxygen valve port.

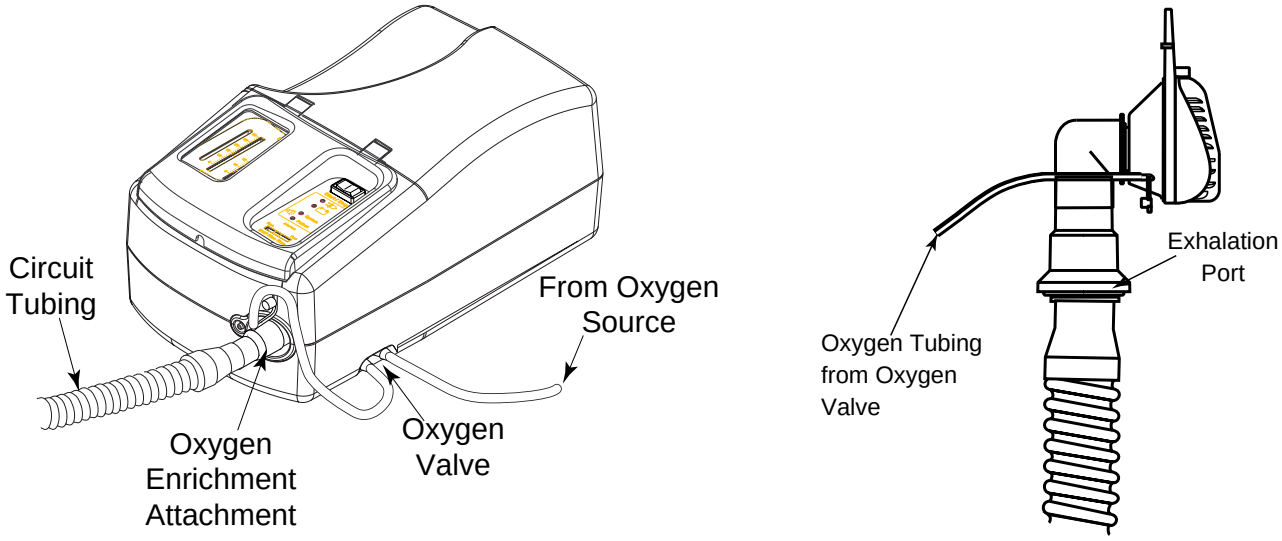


Figure 6-1. Methods of Adding Oxygen to the Patient Circuit.

Step 2 Connect a section of oxygen tubing to the front valve port, then to one of the sample ports on the mask or to an O_2 enrichment adaptor positioned in the patient circuit.

Step 3 Turn the Harmony S/T ventilator on.

Step 4 Turn the oxygen flow to the desired setting.

NOTE: When adding supplemental oxygen to the patient circuit, the flow is gradually adjusted until the patient's oxygenation needs are adequately met. Patient monitoring should consist of patient observation and oximetry or arterial blood gas measurement as directed by the physician. If adequate oxygenation cannot be achieved, an alternate method of delivery should be considered.

6.2 Supplemental Oxygen Concentrations

Figures 6-2 and 6-3 illustrate the potential range of oxygen concentration available to the patient at a given tidal volume, supplemental oxygen flow, and pressure setting. These figures represent bench test results without inadvertent mask leaks when O_2 is administered at the mask. Substantial leaks around the mask may reduce the expected oxygen concentration to below the levels shown in Figures 6-2 and 6-3. This guideline may be used as a starting point for initiating oxygen therapy. Oxygen flow should be gradually adjusted until the patient's oxygen needs are adequately met.

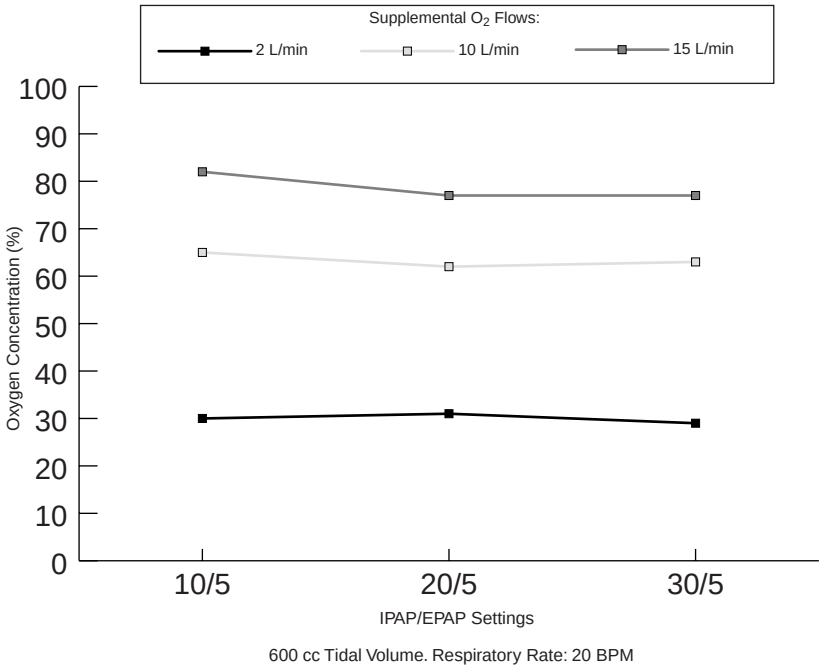


Figure 6-2. Oxygen Concentration for 600cc Tidal Volume.

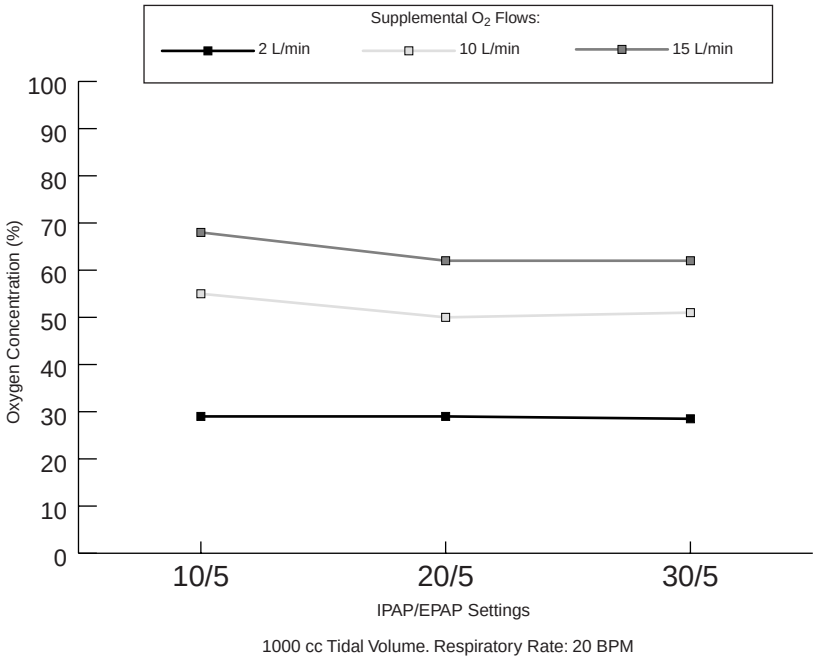


Figure 6-3. Oxygen Concentration for 1000cc Tidal Volume.

Chapter 7: Cleaning and Routine Maintenance

This chapter provides guidelines for the cleaning and maintenance procedures.

7.1 Cleaning the Harmony S/T Ventilator

WARNING: To avoid electric shock, always switch the Harmony S/T ventilator Start/Stop Switch to the STOP position and disconnect the unit from the power source before cleaning or performing any routine maintenance.

CAUTION: Do not immerse the Harmony S/T ventilator or allow any liquid to enter the case or the inlet filter.

NOTE: The following guidelines for cleaning refer to the Harmony S/T ventilator only. To clean the circuit accessories, refer to each accessory's instruction sheet.

STEP 1 Clean the front panel as needed by wiping with a cloth dampened with water or 70% Isopropyl Alcohol only.

STEP 2 Clean the exterior of the enclosure as needed by wiping with an anti-bacterial agent but do not allow liquid to enter the inside of the ventilator.

STEP 3 Allow the unit to dry completely before reconnecting power.

7.2 Cleaning/Replacing the Inlet Filters

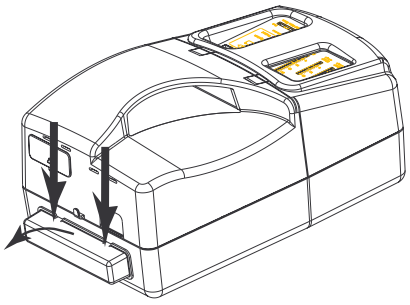
The Harmony S/T ventilator uses two removable filters at the air inlet. The gray pollen filter is washable and reusable. The optional white ultra-fine filter is disposable. Filters may be obtained from the medical device supplier.

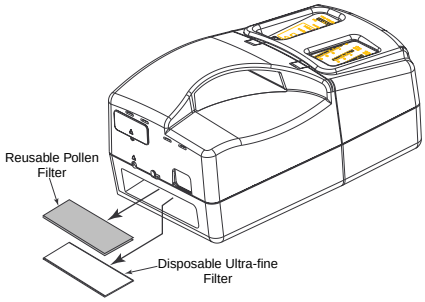
On a monthly basis, clean the gray pollen filter; replace the optional white ultra-fine filter if necessary. Always inspect the filters and replace them if they are damaged.

CAUTION: Dirty inlet filters may cause high operating temperatures and may affect ventilator performance. Examine the inlet filters for integrity and cleanliness monthly or sooner, depending on the operating environment.

STEP 1 Turn the Harmony S/T ventilator Start/Stop Switch to the **STOP** position and disconnect the unit from the power source.

STEP 2 Remove the filter cap by pressing down on the top of the cap to release the tabs, then swinging the cap out from the unit's body.





STEP 3 Remove the filters from the enclosure. The top filter is the reusable gray pollen filter. The bottom filter is the optional disposable white ultra-fine filter.

STEP 4 Examine the filters for cleanliness and integrity.

STEP 5 Wash the pollen filter in warm, soapy water. Rinse thoroughly to remove all soap residue. Allow the filter to completely dry before reinstalling it. If the pollen filter is torn, replace it.

STEP 6 If the ultra-fine filter is dirty or torn, replace it.

STEP 7 Replace the filters with the ultra-fine filter on the bottom.

STEP 8 Replace the filter cap.

Chapter 8: Circuits and Accessories

This chapter details the Respironics-approved breathing circuits and accessories.

8.1 Circuit Configurations

The Harmony S/T ventilator is intended for use with Respironics-approved patient circuits, as illustrated in Figures 8-1 and 8-2. The configuration components are:

- bacteria filter
- 22 mm tubing with a smooth inner lumen
- Respironics interface with integrated exhalation ports or Respironics interface with separate exhalation device.
- heated humidifier

Additional accessories may be added to the circuit to meet specific needs. Every time changes are made to the circuit configuration, the delivered pressures must be monitored with the unit operating.

Respironics circuit connectors comply with ISO 5356-1 or 5356-2.

WARNING: The BiPAP Harmony S/T ventilator requires an intentional leak port, either built into the mask or on a separate exhalation device (e.g., Whisper Swivel II, Plateau Exhalation Valve, or Disposable Exhalation Valve) to remove exhaled air from the circuit. Therefore, specific masks and circuits using an intentional leak port are required for normal operation. The pressurized air from the Harmony S/T ventilator causes a continuous flow of air to exhaust from the leak port to flush the exhaled air from the circuit. The machine should be turned on and the intentional leak port should be checked before using the unit.

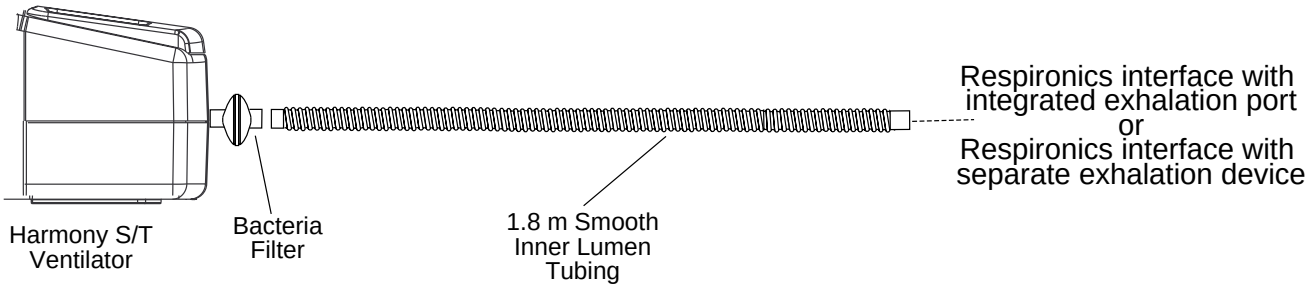

Respironics interface with integrated exhalation port
or
Respironics interface with separate exhalation device
Harmony S/T Ventilator
Bacteria Filter
1.8 m Smooth Inner Lumen Tubing

Figure 8-1. Harmony S/T Standard Circuit.

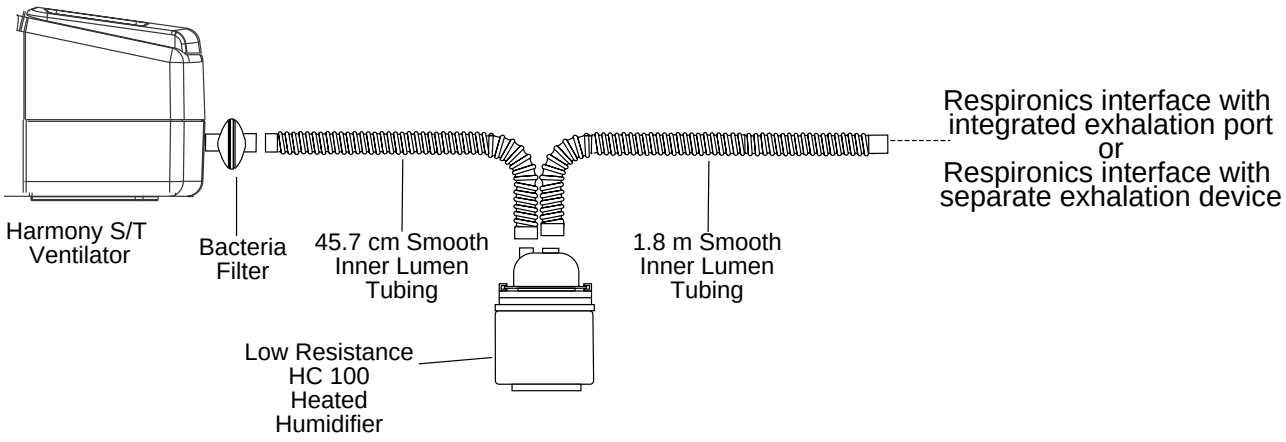

Respironics interface with integrated exhalation port
or
Respironics interface with separate exhalation device
Harmony S/T Ventilator
Bacteria Filter
45.7 cm Smooth Inner Lumen Tubing
1.8 m Smooth Inner Lumen Tubing
Low Resistance HC 100 Heated Humidifier

Figure 8-2. Harmony S/T Circuit with Heated Humidifier.

8.2 Circuits and Accessories

The following accessory items may be used with the BiPAP Harmony System:

—Reusable or Disposable Circuit

Reusable 1.8 m smooth inner lumen tubing, exhalation port.

—Accessories:

15.2 cm disposable circuit tubing
45.7 cm disposable circuit tubing
1.8 m disposable tubing
O_2 enrichment attachment
bacteria filter

8.3 Masks, Exhalation Ports, and Related Accessories

—Masks:

Respironics mask with built-in exhalation ports or Respironics mask with separate exhalation device

—Accessories:

Disposable headgear
Reusable headgear
Chin strap
Softcap™
Slip-on spacers
Quick Clip™
Comfort Flap® mask accessory

8.4 Humidifiers

—Fisher & Paykel HC 100 Heated Humidifier

Chapter 9: Specifications

ENVIRONMENTAL

	Operating	Storage
Temperature	5 °C to 40 °C	-20 °C to 60 °C
Humidity	15 % to 95 % Relative (Non-condensing)	15 % to 95 % Relative (Non-condensing)
Atmospheric Pressure	76.7 to 102 kPa	50 to 102 kPa

PHYSICAL

Dimensions: 29 cm x 18 cm x 14 cm

Weight: 2.9 kg

ELECTRICAL

AC Voltage: 100 to 240 V ~, 50/60 Hz

DC Voltage: 12 V ⎓

AC Current: 1.25 A maximum

DC Current: 5.5 A maximum

Protection against electric shock: Class II Device

Degree of protection against electric shock: Type BF Applied Part

Degree of protection against harmful ingress of water: Ordinary Equipment, IPX0

Modes of Operation: Continuous

Electromagnetic Compatibility: The BiPAP Harmony S/T Ventilatory Support System meets the requirements of EN 60601-1-2.

Fuses: There are no user-replaceable fuses.

PRESSURE

Output: 4 to 30 cm H_2O

Dynamic Regulation: ± 5 cm H_2O

Maximum Achievable Pressure Under Single Fault Condition: 40 cm H_2O

CONTROL ACCURACY

Rate: ± (10 % + 1 BPM) of the set point

TRIGGER SENSITIVITY

Spontaneous Trigger:
—Shape Trigger
—Volume 6 cc above $\dot{V}_{leak}$
—Flow Reversal

Spontaneous Cycle:
—Spontaneous Expiratory Threshold (SET)
—Shape Cycle
—IPAP maximum of 3.0 sec

Control Ranges and Increments

PARAMETER	CONTROL RANGE	TOLERANCE
IPAP	4 to 30 cm H_2O	± (2 + 10%)
EPAP	4 to 15 cm H_2O	± (2 + 10%)
Rate	4 to 30 BPM	± (1 + 10%)
Timed Inspiration	0.5 to 3.0 sec	± (0.1 + 10%)
IPAP Rise Time	600, 300, 100 msec	± 25%

CO_2 Rebreathing Charts

Chart 1 compares the volume of CO_2 rebreathed per breath for a Whisper Swivel or Disposable Exhalation Port and a Plateau Exhalation Valve at various IPAP/EPAP settings.

			Volume of CO_2 Rebreathed per breath	Volume of CO_2 Rebreathed per breath
IPAP	EPAP	V_T	Whisper Swivel/ Disposable Exhalation Port	Plateau Exhalation Valve
8 cm H_2O	4 cm H_2O	400 cc	1.0 cc	0.6 cc
12 cm H_2O	4 cm H_2O	400 cc	1.5 cc	0.6 cc
20 cm H_2O	5 cm H_2O	400 cc	0.3 cc	0.1 cc
20 cm H_2O	10 cm H_2O	400 cc	0.1 cc	0.1 cc
30 cm H_2O	5 cm H_2O	400 cc	1.0 cc	0.2 cc
30 cm H_2O	10 cm H_2O	400 cc	0.1 cc	0.1 cc
8 cm H_2O	4 cm H_2O	800 cc	3.6 cc	1.3 cc
12 cm H_2O	4 cm H_2O	800 cc	3.1 cc	1.4 cc
20 cm H_2O	5 cm H_2O	800 cc	0.5 cc	0.5 cc
20 cm H_2O	10 cm H_2O	800 cc	0.2 cc	0.1 cc
30 cm H_2O	5 cm H_2O	800 cc	0.4 cc	0.3 cc
30 cm H_2O	10 cm H_2O	800 cc	0.2 cc	0.1 cc

Chart 1

NOTE: The information in Chart 1 was generated from laboratory testing using a constant respiratory rate of 20 BPM (1:2 ratio). It does not account for the many variables that can affect the amount of CO_2 rebreathing in actual use (e.g., leak).

Chart 2 compares the volume of CO_2 rebreathed per breath for a Whisper Swivel or Disposable Exhalation Port and a Plateau Exhalation Valve at various inspiration times.

IPAP	EPAP	V_T	% Inspiration Time	Volume of CO_2 Rebreathed per breath: Whisper Swivel/ Disposable Exhalation Port	Volume of CO_2 Rebreathed per breath: Plateau Exhalation Valve
8 cm H_2O	4 cm H_2O	400 cc	23	1.0 cc	0.1 cc
8 cm H_2O	4 cm H_2O	400 cc	33	1.4 cc	0.1 cc
8 cm H_2O	4 cm H_2O	400 cc	50	2.6 cc	0.4 cc
8 cm H_2O	4 cm H_2O	800 cc	23	3.6 cc	0.2 cc
8 cm H_2O	4 cm H_2O	800 cc	33	3.6 cc	0.2 cc
8 cm H_2O	4 cm H_2O	800 cc	50	4.6 cc	1.0 cc

Chart 2

NOTE: The information in Chart 2 was generated from laboratory testing using a constant respiratory rate of 20 BPM (with varying I:E ratios). It does not account for the many variables that can affect the amount of CO_2 rebreathing in actual use (e.g., leak).

Chart 3 provides the approximate total volume of each of the patient interface accessories that can be used with the BiPAP Harmony S/T.

Respironics Patient Interface	**Deadspace Volume**
Petite Nasal Mask	111 cc
Small Nasal Mask	114 cc
Medium-Small Nasal Mask	149 cc
Medium Nasal Mask	154 cc
Medium-Wide Nasal Mask	173 cc
Large-Narrow Nasal Mask	160 cc
Large Nasal Mask	190 cc
Petite Full Face Mask	225 cc
Small Full Face Mask	280 cc
Medium Full Face Mask	400 cc
Large Full Face Mask	532 cc
Mouthpiece Adapter (includes extension tube)	53 cc

Chart 3

NOTE: For comparison purposes, testing for Charts 1 and 2 were conducted using a medium mask.

Chapter 10: Performance Verification

The performance verification allows the home care provider or clinician to verify that the Harmony S/T ventilator is functioning properly. Performance verification should be completed before each new patient setup.

Step 1 Connect the patient circuit to the Harmony S/T as described in Chapter 3 of this manual.

Step 2 Connect a water column or digital manometer to one of the mask ports.

Step 3 Open the control panel door on the front of the Harmony S/T (see section 4.2.1)

Step 4 Set the patient controls as follows:

- IPAP = 10 cm H_2O
- EPAP = 4 cm H_2O
- Rate = 6 BPM
- Timed Inspiration = 1.5 sec
- IPAP Rise Time = Slow

Step 5 Connect the AC inlet to the Harmony S/T and connect the AC line to the appropriate power source. The AC power LED should be illuminated.

Step 6 Simulate a breathing pattern by occluding and opening the patient outlet.

- Verify that the IPAP LED is illuminated during the inspiratory phase and that the EPAP LED is illuminated during the expiratory phase.
- Verify the IPAP and EPAP pressures with the manometer.

Step 7 When you have established an IPAP/EPAP pattern, occlude the patient circuit.

Step 8 Wait for the Harmony S/T to establish a breathing pattern according to the settings of Step 4.

- Verify that the Rate LED is illuminated in the Timed mode.
- Use a stopwatch to verify the accuracy of the Rate setting.

Step 9 Reset the patient controls as follows:

- IPAP = 25 cm H_2O
- EPAP = 15 cm H_2O
- Rate = 30 BPM
- Timed Inspiration = 3.0 sec
- IPAP Rise Time = Fast

Step 10 Repeat steps 6 and 7.

- If all of the parameters are within the stated operating specifications, the system is ready for patient application.
- Adjust the settings to the appropriate level for patient application prior to placing the circuit on the patient.

Step 11 With the START/STOP switch in the START position, disconnect the power cord at the wall outlet.

Verify that a continuous alarm sounds for at least two minutes.

WARNING: If the Harmony S/T ventilator fails to perform within the stated specifications, have the system serviced by a qualified Respironics-approved service facility.

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Limited Warranty

Respironics, Inc. warrants that the BiPAP Harmony S/T ventilator shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of one (1) year from the date of sale by Respironics, Inc. to the dealer. If the product fails to perform in accordance with the product specifications, Respironics, Inc. will repair or replace – at its option – the defective material or part. Respironics, Inc. will pay customary freight charges from Respironics, Inc. to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration, and other defects not related to material or workmanship.

Respironics, Inc. disclaims all liability for economic loss, loss of profits, overhead or consequential damages which may be claimed to arise from any sale or use of this product. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

This warranty is given in lieu of all other express warranties. In addition, any implied warranties—including any warranty of merchantability or fitness for the particular purpose—are limited to one year. Some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you. This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

To exercise your rights under this warranty, contact your local authorized Respironics, Inc. dealer or contact Respironics, Inc. at:

1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668-8550
1-412-731-2100

RESPIRONICS INC.®
1001 Murry Ridge Lane
Murrysville, Pennsylvania
15668-8550 U.S.A.

RESPIRONICS®
Deutschland
Gewerbestrasse 17
82211 Herrsching Germany

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